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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/633,295	08/07/2000	Alfons Nichtl	100564-00025	4590

6449 7590 07/02/2003

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER

DO, PENSEE T

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/02/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/633,295

Applicant(s)

NICHTL, ALFONS

Examiner

Pensee T. Do

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24 and 26-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24, 26-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

The request filed on June 13, 2003 for a Continued Examination under 37 CFR 1.114 based on parent Application No. 09/633,295 is acceptable and an RCE has been established. An action on the RCE follows.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24, 26-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liberti et al. (US 5,597,531) further in view of Nichtl et al. (US 5,972,720).

Liberti teaches a coating process comprising coating a wide range of materials (including dextran, proteins, synthetic polypeptides, polymers, detergents, polyethylene glycol and combinations thereof) onto colloidal magnetically responsive particles to obtain stable microagglomerants. The process comprises the following steps:

(a) forming a liquid mixture of a particulate magnetic starting material and a coating material;

(b) treating the mixture to subdivide the particles of the magnetic starting material;

(c) permitting the coating material to form a coating on the subdivided particles of the magnetic starting material to form stable, resuspendable coated particles;

(d) recovering the resuspended coated magnetic particles from the liquid mixture. (See col. 4, lines 45-52; claim 1).

Liberti also fails to teach an additional stabilizer such as an inert protein or/and polyethylene glycol after loading the colloidal particles and colloidal particles selected from the group consisting of gold, silver, copper, platinum, palladium and mixture thereof. Liberti also fails to teach the concentration of detergent to be 0.001 to 1mM.

Nichtl teaches that after the colloidal particles have been loaded with the respective desired biomolecule, it is necessary to stabilize the conjugates. This stabilization minimizes an aggregation of the particles and to saturate the remaining free surfaces accessible to adsorption. In the state of the art inert proteins, e.g. bovine serum albumin, detergents, and polymers such as polyethylene glycol, polyvinylpyrrolidone, polyvinyl alcohol, polyvinyl sulfate, dextran and gelatin are used as stabilizers. Nichtl also teaches a new stabilizer, thiol-substituted polyethylene glycol, which is added to the conjugate of gold particles or metallic particles such as particles of metals, metal oxides, metal hydroxides, metal compounds or particles coated with metals or metal

compounds. The metal particles are selected from the group consisting of gold, silver, copper, platinum, palladium, and mixture thereof. (see col. 1, lines 47-61; col. 2, lines 25-28; col. 2, line 53-col. 3, line 7).

It would have been obvious to one of ordinary skills in the art to add the an inert protein selected among those taught in Nichtl to the conjugate formed by the method of Liberti since Liberti and Nichtl both teach improving the long-term stability of the conjugates and lowering the aggregation or agglomeration tendency in solution. (see Nichtl col. 2, lines 25-36). Regarding the concentration of the detergent, one of ordinary skill in the art would find it obvious to arrive at an optimum concentration of detergent without the affecting the function of the biomolecules on the particles through routine experimentation.

Response to Arguments

Applicant's arguments filed June 13, 2003 have been fully considered but they are not persuasive.

Regarding the 103(a) rejection, Applicants traverse that Liberti does not teach a coating material in which detergent does not adversely influence the function of the conjugates by displacing the biomolecules or by interacting with the biomolecules or the colloidal particles after loading. Applicants state that "Liberti coatings are clearly described by the authors to "saturate the remaining free surfaces accessible to adsorption". If the coating saturates remaining free surfaces of the biomolecules, the particles or both, then it does not meet the claim limitation which requires that the detergent coating in the present invention does not adversely influence function by

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interacting with the biomolecules or the colloidal particles. The Liberti's coating interacts to the detriment of function.

Nichtl teaches that after loading the particles, it is necessary to stabilize the conjugates. Such stabilization minimizes an aggregation of the particles and saturates the remaining free surfaces accessible to adsorption. Saturating the remaining free surfaces of the biomolecules accessible to adsorption is not adversely influencing the function of the conjugate by interacting with the biomolecules or the colloidal particles or by displacing the biomolecules. Liberti's method teaches a coating of detergents, protein or a combination thereof is coated on the particles and thus meets the requirements of the present invention because with the same components and the same method steps, the results should be the same. Since stabilizing is not an adverse effect, the particle of Liberti meets the limitation of 'the detergent does not adversely influence the function of the conjugates by displacing the biomolecules or by interacting with the biomolecules or the colloidal particles.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Pensee T. Do
Patent examiner
June 27, 2003



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641